MAIN INFORMATION AND CONSENT FORM

Protocol: RV546/WRAIR #2733

Protocol Title:	"Randomized, Double Blind Evaluation of Late Boost Strategies with IHV01 (FLSC in aluminum phosphate) and A244 with or without ALFQ for HIV-uninfected Participants in the HIV Vaccine Trial RV306 / WRAIR 1920"
Sponsor:	The Surgeon General, Department of the Army
Funding Source:	Cooperative Agreement #W81XWH-18-2-0040
Protocol Chair:	Sandhya Vasan, MD Director, HJF Component of MHRP and EIDB Henry M Jackson Foundation (HJF) Tel: +1 301-500-3622 svasan@global-id.org
Principal Investigator:	Punnee Pitisuttithum, MD, DTM&H Chief, Clinical Trials Section Vaccine Trial Centre, Faculty of Tropical Medicine, Mahidol University 420/6 Rajvithi Road, Bangkok, 10400 Thailand Tel: 081 829 4906, 081 700 1890 (24 hours) punnee.pit@mahidol.ac.th LTG. Sorachai Nitayaphan, MD, PhD Senior Researcher Royal Thai Army (RTA), Clinical Research Center Armed Forces Research Institute of Medical Sciences 315/6 Rajvithi Road, Bangkok 10400, Thailand Tel: 081 625 1531, 090 214 3119 (24 hours) sorachain.rta@afrims.org
Chulalongkorn Memorial Hospital and TRCARC Investigator:	Nittaya Phanuphak, MD, PhD SEARCH Office/The Thai Red Cross AIDS Research Centre (TRCARC) 104 Rajdumri Road, Bangkok, Thailand 10330 AND Institute of HIV Research and Innovation (IHRI) Foundation 319 Chamchuri Square Building, 11th Floor, Unit 1109-1116, Phayathai Road, Pathumwan, Bangkok, Thailand 10330 Telephone: 02 253 0966, 02 160 5372, 081 825 3544, 083 010 8544 (24 hours), nittaya.p@ihri.org
IND Number:	27011

Thank you for your interest in this exploratory research study. This study will take place at VTC, FTM, Mahidol University and RTA-AFRIMS, Bangkok. This study is sponsored and funded by the United States Department of Defense. The box below tells you important things you should think about before deciding to join the study. We will provide more detailed information below the box. Please ask questions about any of the information before you decide whether to participate. You may also wish to talk to others (for example, your family, friends, or your

doctor) about this study, before agreeing to join. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

Key Information for You to Consider
• **Voluntary Consent.** You are being asked to volunteer for the RV546 research study because of your enrollment in the RV306 study. It is up to you whether you choose to participate or not. You will not lose any rights to which you are entitled if you decide not to join or if after you join, you decide to quit. • **Purpose.** We are doing this research to test whether delayed boosting (receiving another dose of vaccine) of previous RV306 study participants with different candidate HIV vaccine proteins called IHV01 (FLSC) and A244 will increase the amount and types of antibodies your body makes. The A244 vaccine proteins will be mixed with an aluminum hydroxide fluid gel (AHFG) adjuvant, however some participants may also receive an adjuvant called ALFQ. An adjuvant is a substance that acts to increase immune responses to vaccines. Immune responses occur when your body recognizes and defends itself against foreign substances such bacteria and viruses by making proteins that get rid of the foreign substances. These proteins are called antibodies. Vaccines also cause immune responses, but they help teach your body how to defend itself from a virus without infecting you with the virus. This study will also determine whether boosting with IHV01 (FLSC) and A244 with or without ALFQ is safe. • **Duration.** Your part of the study will last for 12 months after you receive the study vaccine or placebo. • **Procedures and Activities.** If you participate in the study you will receive 2 injections of the study vaccines or placebo into your thigh (quadriceps muscle) at the vaccination visit, record any side effects that you experience for 7 days after receiving the injections, undergo a physical exam, have blood drawn for CBC, Creatinine, Syphilis, Hepatitis B and HIV tests, give a urine sample for urinalysis (blood, protein and glucose) and pregnancy tests, answer questions, and be tested for sexually transmitted infections. You will also be given the opportunity to participate in optional procedures. You can still participate in the study if you decide not to take part in any of the optional procedures. • **Risks.** Most studies have some possible harms that could happen to you if you join. In this study, there may be risks associated with blood draws, the vaccine, or from the possibility of false-positive HIV test results due to the immune response to the vaccine. The most serious risk is the possibility of an allergic or (rare) autoimmune reaction to the vaccine. The clinic has emergency medical equipment in place to handle allergic reactions if they should occur. • **Benefits.** There are no direct benefits for your participation in this study, however the knowledge gained from this study may be beneficial to others in the prevention and or cure of HIV in the future. • **Alternatives.** Participation in this study is voluntary and the only alternative is to not participate.

Why is this research study being done?

The main purpose of this study is to test whether delayed boosting (an extra administration of a vaccine) with the IHV01 (FLSC) protein and A244/AHFG protein with or without ALFQ will cause your body to make higher amounts of antibodies or different types of antibodies after the vaccination. This study is building upon knowledge that was gained from previous studies such as RV144, RV305, and RV306. The RV144 study demonstrated vaccine efficacy, whereas the RV305 and RV306 studies showed that boosting previously vaccinated individuals could cause an immune response even if the boost was done months or over a year after the initial vaccination. The vaccines used in the RV546 study are not the same as those used in prior studies, however they have some similarities. The vaccines in this study are combinations of the following:

A244 is a protein that acts like the outer shell of the HIV virus, and is very similar to one of the two proteins in the AIDSVAX vaccine which you have already received in the RV306 study. The A244 protein has been used in previous studies and has proven to be safe in humans, however a remanufactured version will be used in this study. The remanufactured version has not previously been tested in humans.

IHV01 (FLSC) is a protein that acts like the outer shell of the HIV virus and is coupled to a protein that acts like part of a protein found on white blood cells. This product has been tested in healthy participants in the US and was found to be generally safe, although some people experienced pain, redness and swelling at the injection site which resolved.

ALFQ is Army Liposomal Formulation type Q. It contains cholesterol and soap-molecules and a molecule from tree bark (Q). This adjuvant has been tested in animals and did not cause more than general inflammation (redness and swelling) at the injection site. It has also been tested in humans as part of a malaria vaccine study with preliminary safety reports showing that some participants experienced mild muscle pain, redness, inflammation, pain and tenderness at the injection site, chills, fever, fatigue, and/or a headache. Most side effects were mild and generally resolved within 48 hours after receiving the vaccine injection. The ALFQ adjuvant is also being planned for testing with other non-HIV vaccines in humans.

Aluminum hydroxide fluid gel is a substance that increases immune responses to vaccines, is used in at least 146 vaccines worldwide and has been shown to be safe in humans.

Placebo is an inactive substance. In this trial, participants receiving placebo will be given injections of saline (saltwater).

The products being given in this study are not obtained by collecting them from a person and they are not generated from the HIV virus. They are artificial products manufactured under controlled, clean conditions used for drug manufacturing. As they are not generated from the HIV virus, **you will not be infected with HIV from receiving these vaccines.** These vaccines have not been approved or cleared by the US or Thai FDA, however they have allowed the use of the vaccines in this research study to learn more about its safety and efficacy.

Researchers are inviting volunteers who received vaccinations in the RV306 study with late boosting at month 12, 15, or 18 and who completed all vaccinations to participate in the current study.

Inclusion and exclusion criteria

You will be asked to take part in this study if you are an HIV-negative, prior RV306 participant who was randomized to receive active vaccine with late boosting at month 12, 15, or 18 and who completed all vaccinations. You must be available to join in this study for the entire duration of the study (12 months), have a Thai identity card, and be capable of reading Thai.

After signing the consent form to take part of the study, you will be asked to take a test of understanding to see how much you understand the study. You must answer at least 8 out of 10 questions correctly in order to participate in the study. You may take the test 3 times to get a score of 8 out of 10, however there will be two questions that you must get correct in order to be eligible for study participation. Then the doctor will ask you questions and do a physical examination to see if there is any reason you should not join in the study. You will not be asked to join in this study if you have a history of a HIV, other medical or mental illness that may interfere with your ability to understand the study and give consent to be part of the study, if you have certain other medical conditions such as hepatitis, if you have a history of allergic reactions to any parts of the vaccine, or if you are pregnant or breast-feeding. Blood and urine will be collected to verify that you are eligible to participate in the study. Your eligibility may need to be reassessed at a later date if you have recently received a COVID-19 vaccine but are otherwise eligible for this study. If the investigator determines that you are ineligible for participation due to a temporary condition, then your eligibility can be reassessed once the condition resolves. Conditions that will make you temporarily ineligible include but are not limited to syphilis, gonorrhea, and chlamydia.

You may not be eligible to take part in this study if the results of the screening indicate that you have health problems. A study staff will explain all the details to you including where you can get assistance and treatment. If you have a reproductive system infection or a positive HIV test result, the study staff will provide you with counseling and referral for medical treatment according to your rights to receive health service.

How many participants will join this study?

Researchers will enroll approximately 80 eligible people in this study.

How long will I be in this study?

Participation in this study will require one screening visit, one vaccination visit, and five follow-up visits over the course of 12 months. The vaccination visit will occur 16 to 45 days after the screening visit. If the vaccination visit is not completed within 45 days after the screening visit for any reason, then the screening visit must be repeated to verify your eligibility before you can receive the study vaccine/placebo injections. The five follow-up visits will occur at 1, 7, and 14 days post vaccination and then at 6- and 12-months post vaccination. You will be followed for 12 months post-vaccination for safety and study of your immune response. There may be an additional visit after all participants have completed the study at which the study doctor/staff will inform you about the study results and whether you received the vaccination or the placebo injections.

What are my responsibilities during this study?

If you take part in this study, you will be asked to:

- Provide proof of your identity via a Thai identity card;
- Provide complete and accurate information about your medical history, medication use, and any symptoms or illnesses you have during the study;
- Follow the study staff's instructions and complete your diary card;
- Attend all study appointments and be available for telephone calls from the study staff. If you cannot keep an appointment, contact the study clinic immediately to reschedule.
- If female, avoid pregnancy by not having sex or using appropriate birth control methods (male condoms, hormonal contraception or birth control pills, intrauterine device or IUD, hormonal injections, diaphragms or male partners who have undergone a vasectomy are acceptable methods) for at least 45 days prior to vaccination and for at least 3 months after vaccination. Please inform the study doctor/staff immediately if you do become pregnant during the study;
- If a male who has not undergone a vasectomy and have a female partner of child-bearing potential, take measures to prevent pregnancy such as not having sex or using appropriate birth control methods (male condoms or partner's use of hormonal contraception or birth control pills, intrauterine device or IUD, hormonal injections, or diaphragms are acceptable methods) for at least 3 months after vaccination. Male participants who have undergone a vasectomy are not required to use contraceptive methods;
- Inform the study doctor/staff of any change in your health status, side effects, visits to another doctor/hospital and any changes in your plans or ability to participate in the study;
- Not enroll in ANY other clinical research study while you are in this study.

It is important that you know that this product will not protect you from getting or transmitting HIV to others if you become infected with HIV through sexual intercourse or through exposure to blood (example: sharing needles for drug use). The study staff will provide you with risk reduction counseling at each visit.

What will I be asked to do if I join this research study?

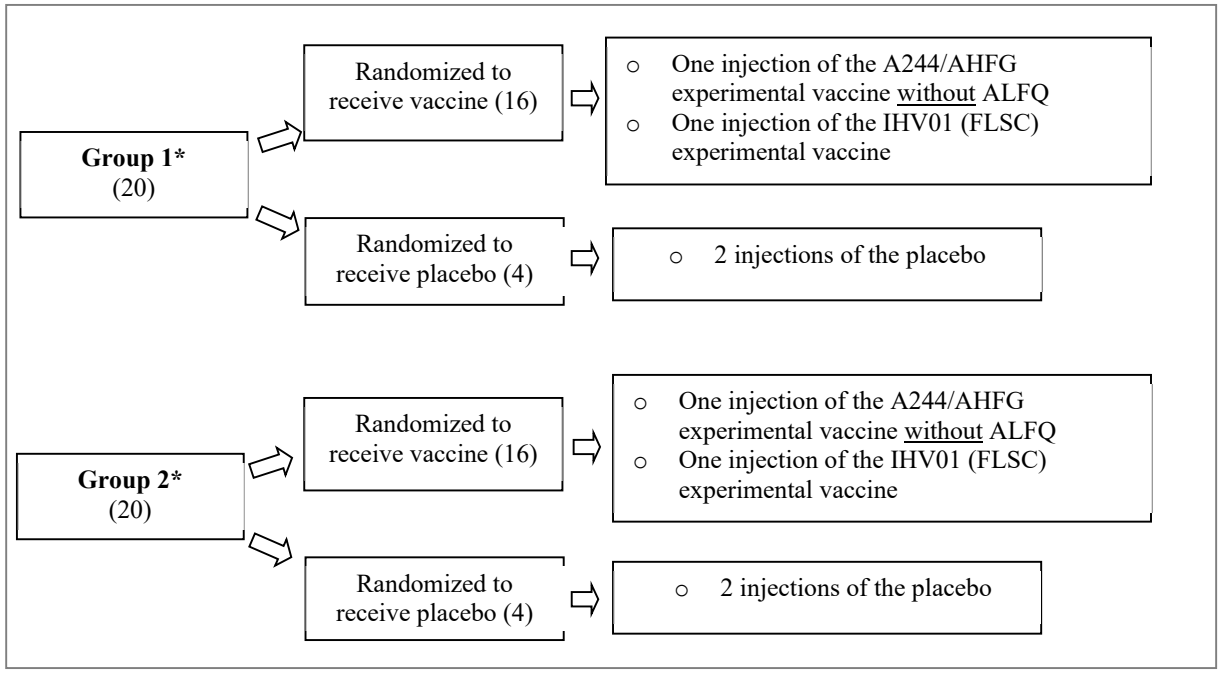
Each time you visit the clinic you will go through study procedures as scheduled, such as screening activities during re-assessment visit, receipt of vaccines or placebos and other associated activities during the vaccination visit, and follow-up activities during the follow-up visits. You will receive a table detailing the activities of each visit.

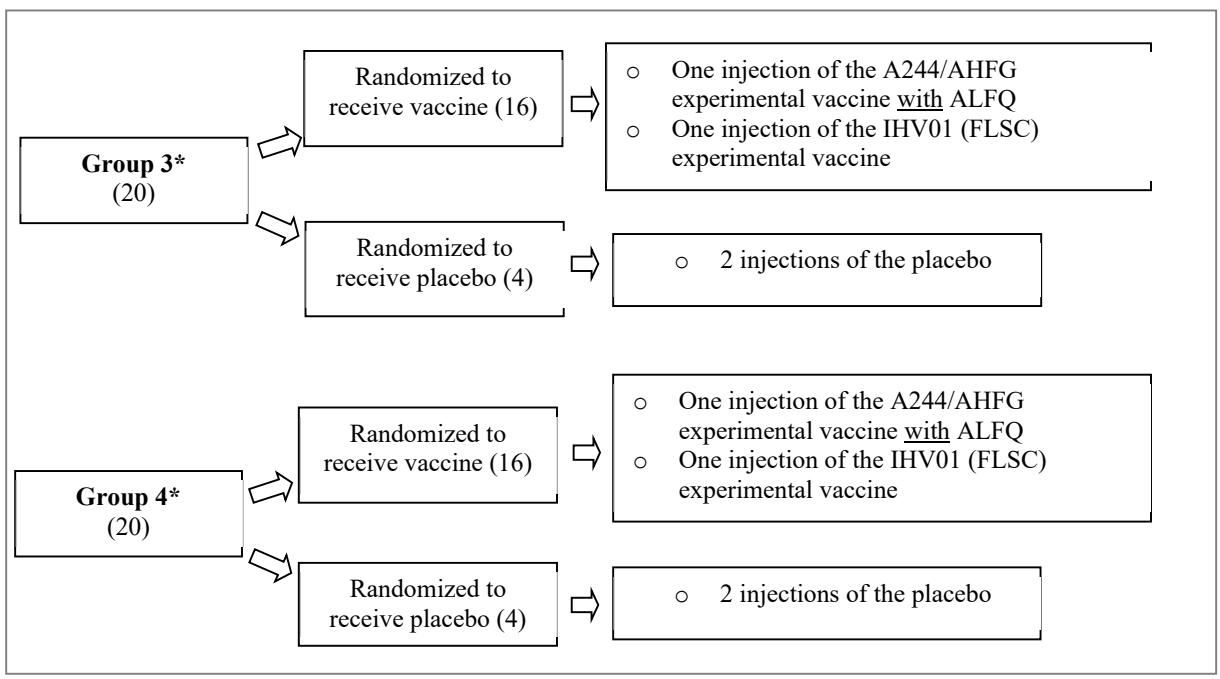
There will be 8 visits including the screening visit. There will be only one vaccination visit, 5 follow-up visits, and a post-study visit. The vaccination visit will take approximately 3-4 hours. Other appointments will take approximately 1-2 hours. However, these do not include additional appointments if you have any side effects and if the study team requests you to come to the clinic.

Schedule of Participants Activities

Visit	**Screening**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Visit Day (enrollment date)	**16 to 45 days before vaccination**	**0**	**1**	**7**	**14**	**168**	**336**	**post database lock**
Visit Week		**0**	**1**	**1**	**2**	**24**	**48**	
Informed Consent	X							Final Results and Unblinding
Test of Understanding	X							
Enrollment and Randomization		X						
Vaccination		X						
Vital Signs and Physical exam	X	X		X	X	X	X	
Medical History & Concomitant Medications	X	X		X	X	X	X	
Adverse Event Documentation		X	X	X	X	X	X	
Diary Card		X	X	X				
HIV Risk Assessment/Risk Counseling	X	X			X	X	X	
Pregnancy Test & Pre/Post Counseling	X	X			X	X	X	
Urinalysis (blood, protein and glucose)	X	X	X	X	X	X	X	
CBC w/ diff & CD4 (ml)	2	2	2	2	2	2	2	
Creatinine, ALT/AST (ml)	3.5			3.5	3.5	3.5	3.5	
Syphilis and Hepatitis B Serology (ml)	3.5							
HIV Testing & Pre/Post Counseling	6				6	6	6	
Research Testing (ml)		126	40	100	126	126	126	
Daily Volume (ml)	15	128	42	105.5	157.5	137.5	137.5	
Daily Volume (ml) for participants under 50kg	15	93	42	70.5	122.5	137.5	137.5	

At the vaccination visit, you will be randomized into one of four study groups and will receive 2 injections of the vaccines or 2 injections of the placebo into the same thigh muscle. Of the 20 participants in each study group, 16 will receive vaccines and 4 will receive placebo, which means that you are 4 times more likely to receive the vaccines as compared to the placebo. However, neither you nor the study staff will know if you receive vaccines or placebo.





* Each group is different in the dosage of the experimental vaccines received.

After the vaccinations, the study staff will observe your symptoms for at least 30 minutes to 1 hour. Also, we will examine your vital signs such as blood pressure and heart rate before you go back home. The investigators will ask you to record how you feel in a diary card (for example, if you have fever, headache, pain, chills, redness, or other symptoms) on the day that you receive the injections and on each of the 7 days following the injections. The study staff will give you a

thermometer to measure body temperature and a ruler to measure the size of any reactions at the vaccine/placebo injection areas.

If you are willing to participate in an optional procedure such as mucosal secretion collections, inguinal (groin) lymph node collection, sigmoid tissue collection or process of white blood cell collection (leukapheresis), it may take longer than the usual visit. You may agree to only one, more than one, all, or none of the procedures. You may decide not to participate in these optional procedures and still participate in the main research study. Additional information about the optional procedures will be provided in each optional procedure informed consent form.

Why might researchers ask me to leave the study before it ends?

Researchers may ask you to leave the study if the sponsor cancels the study or if the medical staff decides it is not good for your health to continue participating in the study. Researchers may ask you to leave for repeated failure to comply with protocol requirements.

What if I want to leave the study before it ends?

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. The final study visit will take about 1 hour. At this visit, researchers may ask to:

- Give you a physical exam
- Ask about any side effects or health problems since your last visit
- Draw a blood sample
- Provide a urine sample
- Ask you to complete questionnaires

Your specimens during the study

In order to meet the Thai National Blood Bank donation policy, the amount of blood drawn during this study will be different between participants who weigh more than 50Kg and participants who weigh 50Kg or less. For all participants, the amount of blood drawn at each visit ranges from approximately 15ml (about 3 teaspoons) to 157.5ml (less than 3/4 cup) depending on the requirements of the visit. Blood will be drawn for safety laboratory testing at about the following amounts: 2ml (about 1/2 teaspoon) for complete blood count and CD4 count, 3.5ml (about 3/4 teaspoon) for kidney and liver function, 3.5ml (about 3/4 teaspoon) for hepatitis B and syphilis testing, and 6ml (about 1/2 tablespoon) for HIV testing.

For participants who weigh more than 50Kg, the total amount of blood drawn over the entire study is up to approximately 723ml (about 3 cups).

The table below shows the amount of blood that will be collected at each visit and cumulative totals over 12-week intervals.

Visit	**Screening**	**1**	**2**	**3**	**4**	**5**	**6**
Visit Day	16 to 45 days before vaccination	**0**	**1**	**7**	**14**	**168**	**336**
Visit Week		**0**	**1**	**1**	**2**	**24**	**48**
Participants who weigh more than 50Kg	15	128	42	105.5	157.5	137.5	137.5
12-Week Cumulative Volume (ml) for more than 50Kg (450ml)					448	137.5	137.5

For participants who weigh 50Kg or less, the total amount of blood drawn over the entire study is approximately 618ml (less than 3 cups).

The table below shows the amount of blood that will be collected at each visit and cumulative totals over 12-week intervals.

Visit	**Screening**	**1**	**2**	**3**	**4**	**5**	**6**
Visit Day	16 to 45 days before vaccination	**0**	**1**	**7**	**14**	**168**	**336**
Visit Week		**0**	**1**	**1**	**2**	**24**	**48**
Participants who weigh 50Kg or less	15	93	42	70.5	122.5	137.5	137.5
12-Week Cumulative Volume (ml) for 50Kg or less (350ml)					343	137.5	137.5

Some of the specimens collected for the study may be used to analyze your DNA gene sequences as they relate to your immune response to the vaccines. Approximately 10ml (about 2 teaspoons) of the blood drawn during the visits listed on the tables above may be used for this DNA analysis. We will not provide the results of these tests to you, as they are not part of a normal medical test, are for research purposes only, and cannot be used to make health-related decisions. You will be provided a separate form to consent or refuse genetic testing on your samples.

Urine will be collected from all participants for screening purposes and from female participants for pregnancy testing. If there is any abnormality found, the study team will inform you immediately.

Samples collected from you during this study will be stored at the AFRIMS Department of Retrovirology SPL, Thailand and/or the US Military HIV Research Program in the USA. The samples will be sent to collaborating laboratories in Thailand and abroad. Specimens will be kept and labeled using a numeric barcode rather than any of your identifiable information, such as your name.

If you withdraw from this study, your specimens and information collected prior to the withdrawal date will be used to study your immune response to the vaccines.

What will happen to my samples after this study?

After the study closes, your remaining specimens will be stored in a secure storage site for 5 years for future research. You will have the opportunity to review, ask questions and provide consent for storage and use of your specimens in the "Informed Consent for the Storage and Future Use of Leftover Specimens" form. Only samples from participants who have provided consent for storage and future use of their samples will be stored at the end of the study. If consent is not provided, the samples will be destroyed upon completion of tests for this study. If the samples need to be kept longer than 5 years, the research team will inform and ask for approval from the responsible organizations as well as the Institutional Review Boards (IRB) and the Ethical Review Committee of Research in Human Subjects, Ministry of Public Health who approved this study. Your stored samples may be used in the future to learn more about how the immune system responds to the vaccine and how vaccines can prevent HIV infection. All future research that uses stored samples must be reviewed and approved by the responsible organizations and the Ethical Review

Committee of Research in Human Subjects, Ministry of Public Health as well as the Institutional Review Boards and Ethics Committees who approved this study.

Whenever possible, a subset of samples will be divided and kept for the Bio-Medical Resources Center, Department of Medical Sciences, Thai Ministry of Public Health after all protocol objectives have been fulfilled. Sending these samples benefits Thailand, therefore samples from all participants will be sent to the Bio-Medical Resources Center as availability permits.

What are the risks of participating in this study?

Blood draws: There is the possibility of pain, bleeding, swelling, or bruising, where the needle enters the arm. There is a rare chance that a local infection can happen where blood was drawn. Rarely, some people can have dizziness or fainting after having blood collected.

Vaccine injection: IHV01 (FLSC) and A244 are the two vaccines in this study. When tested in another human trial, the most common reaction following IHV01 (FLSC) injection was general inflammation (redness and swelling) at the injection site. The remanufactured version of A244 that is used in this study has not been tested in humans and the side effects are not yet fully known. The most common side effects occurring after vaccination with either vaccine or placebo are pain, redness, hardness or swelling, limitation of leg movement, irritation at the site of injection, and skin infections at vaccination area (very rare). You may experience fever, shivering, tiredness or feeling unwell, rash, muscle pain, joint pain, headache, or nausea. These symptoms are similar to those that people have after receiving other preventive vaccinations and should last for only 1-2 days. There might be a chance of severe allergic reaction.

An adjuvant is a substance added to vaccines that can help to make the vaccine more effective by improving the immune response or causing the immune response to last longer than without the adjuvant. The ALFQ product used in this study is an adjuvant or agent that helps boost the body's immune response. Experimental vaccines or adjuvants could uncover or worsen an immune-related disease or syndrome. A variety of experimental HIV vaccine components, like those in this study, have been extensively evaluated in humans and have not caused immune-related diseases. However, study participants will be closely monitored for immune-related diseases. In a malaria vaccine study, the side effects of vaccines that contained ALFQ included mild muscle pain, redness, inflammation, pain and tenderness at the injection site, chills, fever, fatigue, and/or a headache. Most side effects were mild and generally resolved within 48 hours after receiving the vaccine injection.

As with any experimental product administration, there is always the risk of a serious, or even life-threatening, allergic reaction no matter what precautions are taken. Medical emergency equipment is located at each study clinic. This is available to handle emergencies, such as anaphylaxis (severe allergic reaction) and cardiac arrest.

Overall, you may feel tiredness from the procedures being done as part of this study.

Social risks due to vaccination and contact by the study staff

For participants who have received vaccines, routine HIV testing may come back as falsely positive. This false positivity may last from a period of months to years, with the reactivity decreasing through time. This false positivity will eventually disappear, but the length of time that

it takes to disappear is different for each individual. Results from previous HIV vaccine studies have shown that other HIV blood tests can prove that you are not infected with HIV, and that the false positive result is simply a result of the immune response to the vaccine. Thus, you should refrain from having any HIV tests outside of the study clinic. If you want or must do the HIV test outside of the study clinic, we would like you to discuss this with the investigators before doing the test to prevent possible problems if the test is false positive.

If your HIV test result is false positive from an immune response to the vaccine, the study team will perform additional blood tests at your convenience and free of charge, until the false reactivity has disappeared. This testing can continue to be done if you are still false positive even after the study has ended. The investigators will do everything carefully such as using numeric system instead of your name to protect your confidentiality.

Due to the possibility of false positive result, the study team will ask you to stop blood donation during study participation. If you would like to donate blood, the study staff will provide you additional information on the last visit by monitoring the duration of false positive until it disappears. **However, it is possible that you will be refused for blood donation because of participation in HIV vaccine trial and false HIV positive result.**

You may be treated differently by family, friends, colleagues, or other persons since they may think that you have HIV infection/AIDS or are at risk of HIV. You may be refused medical or dental services, employment, insurance, visa, or to be enrolled as a soldier if you have a false positive HIV result.

After you have given your written permission, the study staff will assist you with any unfair treatment because of study participation. The study team will provide counseling and education to family members, friends and others to reduce any potential negative social impact which may occur (if you require). This includes discussion on your behalf with a health insurance company, employer, or other persons to confirm that you have participated in the study. In addition, you will be given a letter that explains your participation in this study and the possibility of a false-positive test result. You will get counseling and advice on how to answer any questions about your participation in the study, including how to manage problems that may occur. Should you need, you will be referred for treatment and care under the same type of treatment and care services used for other illnesses that may occur during study participation.

The study team will follow you, closely through counseling and medical history taking, to promptly become aware if any negative events/impacts occur and provide support as quickly as possible. The study team will also inform the Community Advisory Board (who represents the community) about the progress of the study and seek their opinions.

It remains unknown whether the FLSC or A244 vaccines can prevent HIV infection. Also, you may either receive vaccine or placebo. **Therefore, you should try to avoid behaviors that may put you at risk for HIV infection.**

Confidentiality protection: Researchers work hard to protect your confidentiality. You are assigned a number and all information about your involvement in this study is linked to that number instead of your name. Only researchers involved in the study are able to access this information. Still,

there is the possibility that information on your participation in the HIV vaccine trial or other information collected during this study could be accidentally disclosed to others not involved in this study. This may result in discrimination by your family, employers and community.

Risk of genetic tests:
The greatest risk associated with genetic testing is to your privacy. Genetic test results can be used to provide information about how susceptible you are to certain diseases. Used inappropriately, this information could be discriminatory (for example, by insurance companies). However, the risk of this happening is extremely low, because your results will not be part of your medical records, will only be labeled with your study number rather than any of your personal information, and will not be sufficient to independently identify you as an individual. Neither you nor your doctor will be given the results as the tests are for research purposes only and not used to make health-related decisions. You will be provided a separate form to consent or refuse genetic testing on your samples.

Can I have sex while I am in this study?
You can have sex while you are in this study and you should continue to maintain safe sex practices (such as using a condom). The vaccination you may receive is not known to be protective against HIV transmission.

What will happen if I become pregnant (female participant)?
Male condoms will be made available to you at no cost throughout the study. Other forms of contraception (intrauterine device (IUD), hormonal contraception, diaphragms or male partners who have undergone a vasectomy) are also acceptable. You are encouraged to use multiple methods of contraception together to ensure that they are effective at preventing pregnancy. This can include your use of a diaphragm and a male partner's use of a condom, your use of a contraceptive medication or an IUD and a male partner's use of condoms, and other combinations of methods.

Please tell your doctor immediately if you feel you may be pregnant. If you become pregnant you will continue to attend study visits at the study site, blood will be drawn for safety purposes only. It is unclear about the effect of the vaccine on a pregnancy and the fetus, so the study team will remain in contact you until you give birth, or the pregnancy is terminated. The study doctors will coordinate with your doctor to make sure that you receive appropriate care, including treatment.

Possible genetic effect to the offspring of male participant
The possible effect of these vaccines to the offspring of male participants is unknown. For male participants who have not undergone a vasectomy and who have a female partner who is able to become pregnant, the use of contraception for at least 3 months after receiving the vaccine is required. This includes the use of male condoms or abstinence and/or the use of other forms of contraception (IUD, hormonal contraception, or diaphragms) by your female partner. Male condoms will be made available to you at no cost throughout the study, but you are encouraged to use multiple methods of contraception together to ensure that they are effective at preventing pregnancy. This can include your use of a condom and a female partner's use of a diaphragm, your use of a condom and a female partner's use of contraceptive medication or an IUD, and other combinations of methods.

What is the benefit from participating in this study?
You should not expect any direct benefit from participating in this study. The knowledge gained from this study may be beneficial to others in the prevention and/or cure of HIV disease.

Do I have other options?
You may decide not to take part in this study. You will not lose any rights to which you are entitled if you decide not to join or if after you join, you decide to quit.

Confidentiality
Researchers will make every effort to keep your personal information confidential. A code, which will be known only to study personnel, will be used instead of your name on study records in this study. The code will be stored in a locked place. Only the researchers, medical staff, the sponsor, and the Institutional Review Boards involved in the study can access your private information.

Researchers will keep all study information confidential to the extent that is permitted by applicable law. Researchers will not give information to anyone without your written permission, except as mentioned above. Results of the study will be published and shared with other interested parties (such as local and federal scientists), however the results will not contain your personally identifiable information in accordance with Thai Law.

After the study ends, researchers will keep all the data collected in a secured place. The principal investigators of the study will be responsible for keeping this information secure. If you leave the study, researchers will not collect any new data. Researchers will store the data that was already collected along with the other data from individuals that have completed the study. Data collected from this study will be stored for at least as long as is required by the Official Information Act, B.E. 2540 (1997) and the U.S. FDA regulations. The Official Information Act B.E. 2540 (1997) requires data storage for 20 years and the U.S. FDA regulations require storage for 2 years following the date of U.S. FDA approval for the Investigational Product or for 5 years following the date on which the study results are submitted to the U.S. FDA in support of, or as part of, an application for a research or marketing permit for the Investigational Product.

We will not report any of your health information to the Thai government authority, unless required by Thai law. We do not test for any reportable diseases in this study, however if study staff learn that you have been diagnosed with any reportable diseases or if you are showing signs and symptoms of these diseases then you will be referred for immediate care and your health information will be reported to the Thai government authority.

Study approval and oversight
Several committees monitor this study. These committees make sure that the study is performed ethically and with scientific merit. These committees also make sure that participants are not being hurt by participating in the study and that participants receive medical care if serious problems develop during the study. The study complies with all Thai and U.S. regulations and international guidelines on the conduct of medical research.

Thai Institutional Review Boards, Ethical Committees and the WRAIR IRB have reviewed this study. These boards will follow the study as it progresses to ensure continued compliance with ethical standards. This means that institute and U.S. government representatives may review

research records as part of their responsibility to protect human participants. The sponsor, IRBs, US and Thai FDAs, and the United States Army Medical Research and Development Command (USAMRDC) ORP HRPO representatives may review the study records and access the confidential information about you.

Volunteer Registry Database

The US Army Medical Research and Development Command has a policy to collect data of all volunteers who participate in this study to be entered into a "Command's Volunteer Registry Database". There are two objectives for this database collection; 1) to answer the questions of volunteers who participate in the study supported by the USAMRDC and 2) to ensure that the study participants are informed of risks or new information as it becomes available.

The required information is as follows:

- Name and last name
- ID Number
- Date of birth
- Contact information
- Study title, date participating in the study as well as withdrawal reason
- Serious unexpected adverse reaction and adverse events related to the vaccine occurring during study participation
- Details of study products you received

This database containing information of Thai participants who participate in this study will be stored in Thailand for 75 years under the responsibility of Armed Forces Research Institute of Medical Sciences, Thailand in coordination with the Faculty of Tropical Medicine, Mahidol University. The database will be kept according to Personal Data Protection Act (PDPA), B.E. 2562 (2019). However, name, surname and ID number will be stored confidentially and separately from the volunteer registry database. This database will not be used for research.

Clinical Trial Information

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are the costs to you?

You will not have to pay for medical visits, hospitalizations, physical examinations, medical procedures or blood tests related to this study. The study team will support costs related to your participation.

Will I get any payment for transportation and loss of time?

For each visit, you will receive 1000 Baht as reimbursement for food and travel costs, lost work time and discomfort. You will receive 1000 Baht for each unscheduled visit that is necessary to address safety concerns, at the investigator's discretion.

Other than medical care that may be provided and any other payment specifically stated in this informed consent, there is no other compensation available for your participation in this research study; however, you should also understand that this is not a waiver or release of your legal rights.

What will happen if I am injured?

If you get sick or injured from taking part in the study, please contact the study team immediately. You will receive appropriate medical treatment here at the study clinic or you will be referred to a qualified medical facility for further treatment and care. Regardless of where you are treated, the study team will continue to provide health care counseling and guidance regarding the appropriate treatment. The cost of the medical treatment and care for the research-related injury or sickness will be covered by a limited fund and a clinical trials medical insurance policy. While we anticipate that the combination of the set-aside fund and the insurance policy is more than enough to pay for the cost associated with this study, there is a limit to the amount of coverage available. Your personal insurance coverage schemes will not be used to cover the cost of medical treatment. The study team will support costs related to participation. Other than medical care that may be provided and other payment specifically stated in this form, there is no other compensation available for you taking part in this study; however, you may pursue your legal right in accordance with Thai law to ask for other compensation relating to research related injury.

You should discuss this thoroughly with the Principal Investigator or site clinicians before making a decision to participate in this study. If you have any questions about study-related sickness or injury, you can contact your study site Principal Investigator:

Punnee Pitisuttithum, MD, DTM&H
Chief, Clinical Trials Section
Vaccine Trial Centre, Faculty of Tropical Medicine, Mahidol University
420/6 Rajvithi Road, Bangkok, 10400 Thailand
Tel: 081 829 4906, 081 700 1890 (24 hours)
punnee.pit@mahidol.ac.th

LTG. Sorachai Nitayaphan, MD, PhD
Royal Thai Army, Clinical Research Center, AFRIMS
315/6 Rajvithi Road, Bangkok 10400, Thailand
Tel: 081 625 1531, 090 214 3119 (24 hours)
sorachain.rta@afrims.org

What if the researchers learn new information during this study?

Result of this study or other scientific research may affect your willingness to continue to take part in this study. During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

We may contact you after the study ends if we have other information related to this research.

What if I have additional questions?

If you have any question about this study or if you have any problems or questions related to the study, you can contact your study site Principal Investigator:

Punnee Pitisuttithum, MD, DTM&H
Chief, Clinical Trials Section
Vaccine Trial Centre, Faculty of Tropical Medicine, Mahidol University
420/6 Rajvithi Road, Bangkok, 10400 Thailand
Tel: 081 829 4906, 081 700 1890 (24 hours)
punnee.pit@mahidol.ac.th

LTG. Sorachai Nitayaphan, MD, PhD
Royal Thai Army, Clinical Research Center, AFRIMS
315/6 Rajvithi Road, Bangkok 10400, Thailand
Tel: 081 625 1531, 090 214 3119 (24 hours)
sorachain.rta@afrims.org

What are my rights as study participant?

As a study participant, you will have the following rights.

1. Researchers will inform you of the purpose, objectives or reason for this study.
2. Researchers will explain to you the medical research procedures, including vaccines and instruments to be used in this study.
3. Researchers will explain to you the possible risks and discomforts of participating in this study.
4. Researchers will explain to you the possible benefits of participating in this study.
5. Researchers will explain to you treatment and care options other than volunteering for this studying, including their risks and benefits.
6. Researchers will answer your questions about this study and all study procedures.
7. Researchers will respect your right to withdraw from this study at any time for any reason without affecting the care you receive now or in the future.
8. Researchers will provide you with a copy of the signed and dated consent form.
9. You have the right to make a decision as to whether or not to participate in this study without influence, threat or deception.

If you have any question and need to ask about your rights, or you do not get appropriate treatment and care for adverse events which occur as a result of taking part in this study, or believe that you are not treated fairly in accordance with what is described in the information sheet, you may make a complaint to the following bodies:

Royal Thai Army Medical Department IRB
5th floor, Phramongkutklaovejvithaya Building
Phramongkutklao Medical School
315 Rajvithi Road,
Bangkok 10400, Thailand
Tel: 02 354 7600, Ext 94270; 02 763 4297
Fax: 02 354 9011
irbrta@yahoo.com

Ethics Committee of the Faculty of Tropical Medicine
Mahidol University c/o Research and Academic Services
4th Floor, The 60th Anniversary of His Majesty the King's Accession of the Throne Building
Faculty of Tropical Medicine, Mahidol University
420/6 Rajvithi Road,
Bangkok 10400, Thailand
Tel: 02 354 9100-4 extension 1349, 1525
Fax: 02 306 9126
tmectropmed@mahidol.ac.th

The Ethical Review Committee of Research in Human Subjects
Ministry of Public Health,
Office of the Secretary, Building 2, 3rd Floor, Department of Medicine Services Building,
Tiwanon Road, Nonthaburi 11000,
Tel: 02 590 6171-2
Fax: 02 591 8251
ecmoph@gmail.com

The Institutional Review Board,
Faculty of Medicine, Chulalongkorn University
1873, 3rd Floor, Ananthamahidol building,
Rama IV Rd., Patumwan,
Bangkok, Thailand
Tel: 02 256 4493
Fax: 02 255 4493
medchulairb@chula.ac.th

Consent form for Study Participants

Protocol: RV546/WRAIR #2733

"Randomized, Double Blind Evaluation of Late Boost Strategies with IHV01 (FLSC in aluminum phosphate) and A244 with or without ALFQ for HIV-uninfected Participants in the HIV Vaccine Trial RV306 / WRAIR1920"

Date of consent: Date_____ Month _____ Year _____

Before signing this consent form, the research staff explained in detail the objectives of the study, the study procedures, the dangers or symptoms that may arise from the study, and the benefits that may arise from the study. They answered all my questions to my satisfaction.

I voluntarily participate in this research project. It has been explained to me that I have a right to end my participation in this research project at any time and without losing any rights to which I am entitled. It has also been explained to me that participation in this study requires HIV testing and that my signature below indicates my consent for willingness to be tested for HIV.

The investigator assured me that my personal information including my name, surname, ID number, date of birth, and contact information will be kept confidential. Data collected during this study will be disclosed in the form of summary results and only with the approval of the staff that support or oversee this research.

I am aware that I do not give up any legal rights by signing this document. If I have questions about this study or are injured from the study, I can contact my study site Principal Investigator:

Dr. Punnee Pitisuttithum
Vaccine Trial Center
Faculty of Tropical Medicine, Mahidol University
420/6 Rajvithi Road, Bangkok
Tel. 081 829 4906, 081 700 1890 (24 hours)
punee.pit@mahidol.ac.th

LTG. Dr. Sorachai Nitayaphan
Senior Researcher
Royal Thai Army (RTA), Clinical Research Center
Armed Forces Research Institute of Medical Sciences
315/6 Rajvithi Road, Bangkok
Tel. 081 625 1531, 090 214 3119 (24 hours)
sorachain.rta@afrims.org

If you cannot reach Dr. Sorachai Nitayaphan/Dr. Punnee Pitisuttithum please contact 090 214 3119 (RTA CRC)/ 081 700 1890 (VTC), at any time 24 hours a day.

I have been given a signed copy of the Consent to Participate in this study to keep which has the same information as the investigator's copy.

I have read the information above, fully agree and willingly sign this consent form.

Volunteer:

Signature _____ Date_____

Printed name (_____)

Signature of the officer who performs consenting:

Signature _____ Date_____

Printed name (_____)

Witness to consenting process:

Signature _____ Date_____

Printed name (_____)

Optional: I choose not to have a witness or witnesses during the consenting process

Signature _____ Date_____

Printed name (_____)

Signature of the officer who performs consenting:

Signature _____ Date_____

Printed name (_____)